PB85-175495

Special Review of Certain Pesticide Products Captafol: Position Document 1

(U.S.) Environmental Protection Agency
Washington, DC

19 Dec 84

U.S. Department of Commerce
National Technical Information Service
NTIS

50272-101

REPORT DOCUMENTATION PAGE	1. REPORT NO.	2.	3. PB85-175495
4. Title and Subtitle SPECIAL REVIEW OF CERTAIN PESTICIDE PRODUCTS CAPTAFOL POSITION DOCUMENT 1			5. Report ISSUED 12/19/84
			6. 540/9-84-011
7. Author(s) EPA, OPP, REGISTRATION DIVISION			8. Performing Organization Rept. No.
9. Performing Organization Name and Address ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDE PROGRAMS WASHINGTON, D.C. 20460			10. Project/Task/Work Unit No. 11. Contract(C) or Grant(G) No. (C) (G)
12. Sponsoring Organization Name and Address same as #9			13. Type of Report & Period Covered 14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This Position Document 1 (PD 1) is the official announcement that EPA is initiating a special review of all pesticide products containing the active ingredient Captafol. EPA has determined that Captafol, which is a fungicide used to control the foliar diseases of certain fruits and vegetables, is oncogenic in rats and mice and highly toxic to fish; and meets or exceeds the risk criteria as described in 40 CFR 162.11, the regulations governing the Special Review (RPAR) process. Only after carefully considering the risks and benefits of Captafol and determining that the pesticide will cause unreasonable adverse effects on man or on the environment, will EPA issue a notice of intent to cancel.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

REPRODUCED BY
NATIONAL TECHNICAL
INFORMATION SERVICE
U.S. DEPARTMENT OF COMMERCE
SPRINGFIELD, VA. 22161

18. Availability Statement	19. Security Class (This Report)	21. No. of Pages
freely available	unclassified	25
	20. Security Class (This Page)	22. Price

(See ANSI-Z39.18) See Instructions on Reverse

OPTIONAL FORM 272 (4-77)
(Formerly NTIS-35)
Department of Commerce

6560-50

ENVIRONMENTAL PROTECTION AGENCY

[OPP-30000/43]

CAPTAFOL

SPECIAL REVIEW OF CERTAIN PESTICIDE PRODUCTS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces that EPA is initiating a Special Review of all pesticide products containing the active ingredient captafol. Captafol is a fungicide used to control the foliar diseases of certain fruits and vegetables. EPA has determined that captafol is oncogenic in rats and mice and is highly toxic to fish. Captafol meets or exceeds the risk criteria as described in 40 CFR 162.11. Accordingly, a Special Review of products containing captafol is appropriate to determine whether additional regulatory actions, if any, are required. During the Special Review process, EPA will carefully examine the risks and benefits of using captafol products.

DATE: Comments, evidence to rebut the presumptions in this Notice, and other relevant information must be received 45 days from the date this notice is received or until (insert date 45 days after date of publication in the FEDERAL REGISTER) (whichever is later).

84P-4086

ADDRESS: Written comments identified as "OPP-30000/43" should be sent by mail to:

Information Services Section,
Program Management and Support Division (TS-757C),
Office of Pesticide Programs,
Environmental Protection Agency,
401 M St., SW.,
Washington, D.C. 20460.

In person, bring comments to:

Rm. 236, CM #2,
1921 Jefferson Davis Highway,
Arlington, VA.

Information submitted in any comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment not containing material claimed to be CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice to the submitter. All non-CBI written comments will be available for public inspection in Rm. 236 at the Virginia address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail:

Ingrid M. Sunzenauer,
Registration Division (TS-767C),
Office of Pesticide Programs,
Environmental Protection Agency,
401 M St., SW.,
Washington, D.C. 20460.
Office location and telephone number:
Rm. 717, CM #2,
1921 Jefferson Davis Highway,
Arlington, VA,
(703-557-7400).

SUPPLEMENTARY INFORMATION: The term "Special Review" is the name now being used by EPA for the process previously called the Rebuttable Presumption Against Registration (RPAR) process. Modifications in the process will be proposed in regulations in the near future. Until other applicable final regulations are adopted, the present Special Review will adhere to RPAR procedures now in effect and set forth in 40 CFR 162.11.

EPA has determined that a Special Review will be conducted for all pesticide products containing captafol as an active ingredient. EPA has also determined that data necessary to refine the Agency's risk analysis for oncogenicity and ecological effects must be developed on an accelerated basis, and that precautionary labeling is required to reduce risk during the Special Review process.

Issuance of this notice means that potential hazards associated with the use of captafol have been identified. These hazards will be examined further to determine the nature and extent of the risk, and considering the benefits of captafol, whether such risks cause unreasonable adverse effects on the environment.

A document entitled "Guidance for the Interim Registration of Pesticide Products Containing Captafol As The Active Ingredient" (Guidance Document) has been issued. (The Guidance Document is also referred to as a Registration Standard.) The Guidance Document is available to the public from the contact person named above. The Guidance Document explains the basis of EPA's decision to start a Special Review and also contains references, background information, data requirements, and other information pertinent to the continued registration of pesticides containing captafol.

I. INITIATION OF A SPECIAL REVIEW

A. GENERAL

A pesticide product may be sold or distributed in the United States only if it is registered or exempt from registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended (7 U.S.C. 136 et seq.). Before a product can be registered, it must be shown that it can be used without "unreasonable adverse effects on the environment" (FIFRA section 3(c)(5)), that is, without causing "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs

and benefits of the use of the pesticide" (FIFRA section 2(bb)). The burden of proving that a pesticide meets this standard for registration is on the proponent of initial or continued registration. If at any time the Agency determines that a pesticide no longer meets this standard for registration, then the Administrator may cancel the registration under section 6 of FIFRA.

The Agency has created an administrative process for fully evaluating whether a registered pesticide may not satisfy the statutory standard for registration. This Special Review process provides a procedure through which EPA may gather and evaluate information about the risks and benefits of a pesticide's use. It also provides a means by which interested members of the public may comment on and participate in EPA's decision making process. The regulations governing this process are set forth at 40 CFR 162.11.

A Special Review is begun when EPA determines that a pesticide meets or exceeds one or more of the risk criteria set out in the regulations (40 CFR 162.11(a)(3)). The Agency generally announces the beginning of the Special Review by issuing a Position Document (PD) 1, which is published in the FEDERAL REGISTER. In addition, registrants of affected products will receive the PD 1 by certified mail. Registrants and other interested persons are invited to scrutinize the basis for the Agency's decision to initiate the Special Review and to submit data and information which rebuts or supports the Agency's determination of risk. Commenters

may also suggest methods to reduce risks of use of the pesticide. In addition to addressing risk issues, commenters are encouraged to submit evidence and discussions of the biological, economic, social, and environmental costs and benefits of use of the pesticide. The public participation stage is described in more detail in Unit V. This notice constitutes PD 1 for pesticide products containing captafol.

If risk issues are not satisfactorily resolved, EPA will proceed to evaluate the risks and benefits of captafol to determine whether to propose regulatory actions to reduce the risks. After providing an opportunity for comment by the Scientific Advisory Panel, the Secretary of Agriculture, registrants, and the public on those actions and the reasons for them, EPA will issue an appropriate final notice. If EPA determines that the risks of use exceed the benefits, EPA will issue a notice of intent to cancel the registration of products intended for such use. The notice may state the intention to cancel registrations outright or it may require certain changes in the composition, packaging, application methods and/or labeling of the product. These changes would be intended to reduce the risks to levels that when considered against the benefits will not pose unreasonable adverse effects on the environment.

A notice initiating a Special Review is not a notice of intent to cancel the registration of a pesticide, and a Special Review may or may not lead to cancellation. This notice initiating the Special Review for captafol products is an announcement of EPA's concern about the safety of the

pesticide's use, and only after carefully considering the risks and benefits of the pesticide and determining that the pesticide appears to cause unreasonable adverse effects on the environment, would EPA issue a notice of intent to cancel.

B. PRESUMPTION

EPA has determined that the use of pesticide products containing captafol meets or exceeds the risk criteria for oncogenicity and hazard to wildlife. In Units I.B.1 and 2, the Agency's concerns over captafol's oncogenic and wildlife effects are discussed.

1. ONCOGENICITY

EPA has determined that captafol meets or exceeds the risk criterion in 40 CFR 162.11(a)(3)(ii)(A). That section provides that a Special Review shall be conducted if the use of a pesticide "induces oncogenic effects in experimental mammalian species or in man as a result of oral, inhalation or dermal exposure...." On the basis of the scientific studies and information summarized in the Guidance Document and briefly discussed below, EPA has concluded that captafol meets or exceeds this risk criterion.

A 2-year mouse study showed dose-related oncogenic lesions in the middle and high dose groups and dose-related non-oncogenic lesions in all dose groups. Oncogenic lesions included lymphosarcomas, myeloproliferative disease, harderian gland hyperplasia, benign harderian gland adenomas, and hemangiosarcomas.

A 2-year rat feeding study showed a dose-related increased incidence of fibroadenomas of the mammary gland and

an increased incidence of neoplastic nodules in the liver of females.

Using the linearized multi-stage quantitative risk extrapolation model, the Agency calculated a preliminary risk assessment. Dietary and non-dietary risks based on the incidence of neoplastic liver lesions in female rats and lymphosarcomas in mice were estimated. The Q* for neoplastic liver lesions in female rats is 5×10^{-2}. The Q* for lymphosarcomas in mice depends upon the sex and number of dose groups used but ranges from 5×10^{-3} to 5×10^{-2}. The Agency is using 10^{-2} as the slope in the preliminary risk calculations. The dietary estimate assumes a uniform distribution of treated crops among the U.S. population and an average daily consumption of those crops by individuals. Although an individual's exposure could vary considerably depending upon eating habits and geographic location, the dietary exposure values are considered representative for the total U.S. population over a lifetime. Because of the lack of residue data, the dietary exposure estimate was based on the assumption that residues are at 100 percent tolerance levels. Tolerances are the maximum residue levels permitted on crops by EPA. This estimate resulted in an upper bound estimate on the excess lifetime cancer risk of 2×10^{-4} from dietary exposure. In the Guidance Document, the Agency estimated non-dietary risk to mixer/loaders and applicators. Because of the lack of data at the time, the Agency assumed 100 percent dermal penetration and used surrogate data from many pesticides to estimate worker exposure. The preliminary

risk estimates resulted in a risk ranging from 3×10^{-2} to 2×10^{-6}. Based on these risk estimates, the Agency announced in the Guidance Document that protective clothing, restricted use classification and a label warning concerning tumors would be imposed to reduce the risk to workers. Following publication of the Guidance Document, the Agency reviewed recently submitted dermal penetration and worker exposure studies, which the Agency evaluated and considered in recalculating worker risk. The dermal penetration study was conducted by applying technical captafol and a formulated product to the skin of male rats. The results indicated that very little was absorbed. The absorption rate was approximately 0.1 percent per hour.

Data from the worker exposure study were not used by the Agency in its exposure calculations because the sample size in that study was too small to produce reliable results. The Agency is confident that its surrogate data, which are based on many studies involving a large sampling of individuals, is a reliable basis upon which to estimate worker exposure to captafol. It is worth noting, however, that the exposure values from the study were generally consistent with the Agency's estimates based on its surrogate data.

The Agency recalculated the risk assessment using the dermal absorption rates shown in the dermal penetration study rather than assuming 100 percent. However, the same exposure estimates based on surrogate data and the same assumptions used in the Guidance document were again used for the new calculations. The results of these calculations

showed an upper limit of excess lifetime cancer risk for workers ranging from 1×10^{-5} to 1×10^{-7}. The risk calculated for the most common application methods ranged from 1×10^{-5} to 8×10^{-6}.

The requirement for protective clothing reduces this risk to workers by almost another order of magnitude. Specifically, the Guidance Document required workers to wear impervious gloves and full body clothing during handling and application. The Agency is revising this requirement to replace "impervious gloves" with "mid-forearm to elbow length chemical resistant gloves." The Agency is also requiring registrants to submit data concerning the type of glove which provides the most protection from captafol. Because inhalation is still an important route of exposure for mixer/loaders, the Agency is requiring that workers who mix and load captafol wear a dust mask.

In the Guidance Document the Agency also classified captafol for "restricted use," which means that only certified applicators trained for and familiar with pesticide use, or persons under their direct supervision, may use captafol. This action was based on the higher cancer risks previously estimated in the Guidance Document. However, the Agency is lifting this restriction because the new risk estimates show that hazards to workers applying this pesticide are much less than originally estimated.

The Agency also required registrants to place a statement on the label of captafol products to warn workers that captafol causes tumors in laboratory animals. Based on revised risk estimates, the Agency believes that risks which may occur during the period of Special Review do not warrant this label warning. During the Special Review the Agency will evaluate whether the long-term risk to applicators justifies the need for any label warning.

2. WILDLIFE

The Agency has determined that the use of pesticide products containing captafol meets or exceeds the risk criteria in 40 CFR 162.11(a)(3)(i)(B)(3) and 162.11(a)(3)(ii)(C). The first criterion provides that a Special Review shall be conducted if the use of a pesticide "results in a maximum calculated concentration following direct application to a 6-inch layer of water more than one-half the acute LC_{50} for aquatic organisms likely to be exposed...." The second criterion requires a Special Review if the use of a pesticide "can reasonably be anticipated to result in significant local, regional, or national population reductions in non-target organisms, or fatality to members of endangered species." On the basis of the scientific studies and information summarized in the Guidance Document, EPA has concluded that captafol meets or exceeds these risk criteria.

The Agency reviewed several valid ecological effects studies which characterize captafol as very highly toxic to fish. Using captafol, the median lethal concentration which

kills 50 percent of the test organisms (LC_{50}) after 96 hours ranged from 0.045 to 0.230 parts per million (ppm) for bluegill sunfish and 0.027 to 0.190 ppm for rainbow trout. These data demonstrate that captafol is very highly toxic to fish.

As a result of this toxicity, the Agency is concerned about the effect of captafol on fish as a result of drift and/or runoff during application to cranberries and citrus groves. The Agency is also evaluating potential hazards of captafol to endangered species.

Captafol used in cranberry bogs irrigated by sprinkler systems or by flooding may present a hazard to fish. Biological monitoring studies in New Jersey detected fish kills after the application of captafol.

Citrus grove applications may present a hazard based on current use practices. In groves where captafol treated trees are irrigated with overhead systems, runoff may result from dislodgement of residues from foliage. This is of particular concern where groves are located near open water. Captafol may also enter open water as a result of drift from applications by way of airblast equipment.

The Agency used a spray drift model to calculate the potential amount of captafol to which fish may be exposed from airblast application to citrus. The expected residues and effects on fish in a 1-acre pond and an estuary representing one-half acre foot of water were estimated. The expected residues in both the pond and estuary exceeded the LC_{50} for fish.

A runoff model using a 6-foot deep 1-acre pond was used to estimate the expected residues of captafol in water

from overhead irrigation in captafol-treated citrus groves. Again for both the pond and estuary, the LC_{50} values for fish were exceeded.

C. RISK REDUCTION MEASURES AND REGULATORY STATUS

Because of the Agency's concerns, the Guidance Document required registrants to change product labeling. These changes include:

1. Additional environmental labeling.
2. An interim 24 hour reentry interval.
3. A prohibition against crops treated with captafol being rotated with crops not registered for captafol use.
4. A prohibition against water from cranberry bogs, wetland taro fields which are foliarly treated, and rice fields planted with captafol-treated rice seed being used for irrigation of crops other than those with registered captafol uses.
5. Specific greenhouse application procedures.
6. "Restricted Use" classification.
7. A tumor warning statement.
8. Protective clothing requirement.

As discussed in Unit I.B.1, the requirements for "restricted use" classification and the tumor warning are being lifted.

The protective clothing requirement is being modified to require all workers to wear mid-forearm to elbow length chemical resistant gloves and full body clothing. Mixer/loaders are being required to wear dust masks. Registrants are also

required to conduct studies to determine what type of gloves provide the most protection from captafol.

The Guidance Document requires registrants to submit studies which will be used to refine the Agency's risk analysis for oncogenicity. Included are toxicology and residue chemistry data. EPA is requiring that these studies be conducted on an expedited schedule of 6 months to 1 year, depending on the test, and will include the results in the PD 2/3. Studies needed to refine the analysis for acute and chronic fish effects are also being expedited. For acute effects, EPA is requiring that these studies be conducted within 1 year. Depending on the outcome of these studies EPA will conclude whether acute effects on fish are of concern; if they are, the Agency will require extensive field testing. For chronic effects, EPA is requiring data related to the environmental fate of captafol. Depending on the outcome of the short-term studies, EPA will determine whether additional data are needed to assess the chronic risk to fish. The following Table 1 describes the pivotal studies needed for both oncogenic and wildlife concerns.

TABLE 1--DATA PIVOTAL TO THE SPECIAL REVIEW

Data Requirements	Submission Date
Studies Pivotal to Oncogenicity	
Residue Chemistry	September 1985
Oncogenicity Study[1/]	September 1985
Studies Pivotal to Acute Fish Concerns	
Acute Toxicity, Estuarine, and Marine Organisms	March 1985
Aquatic Residue Monitoring/ Caged Fish Study	September 1985
Field Testing	Reserved[2/]
Studies Pivotal to Chronic Fish Concerns	
Solubility	March 1985
Vapor Pressure	March 1985
Octanol/Water Partition Coefficient	March 1985
Hydrolysis	March 1985
Photodegradation	March 1985
Leaching	March 1985
Adsorption/Desorption	March 1985
Aerobic and Anaerobic Soil Metabolism	September 1986
Soil Dissipation	September 1986
Chronic Fish Studies	Reserved[3/]

1/ The original study was incomplete. Information concerning control groups and histopathology are needed.

2/ Contingent on the results of the Aquatic Residue Monitoring/ Caged Fish Study

3/ Contingent on the results of the product chemistry and environmental fate studies.

All currently registered products will remain registered while the Special Review is in progress. The Agency is deferring final decisions on the reregistration of any products containing captafol as a sole active ingredient until the Agency concludes the Special Review. The Agency will not register any new uses of captafol until the Special Review is completed. The Agency will also not approve pending tolerance requests or future requests for new tolerances for captafol during the Special Review.

D. REBUTTAL CRITERIA

All registrants, applicants for registration, and other interested members of the public are invited to submit evidence either to support or to rebut the presumption that (1) captafol causes oncogenic effects in rats and mice and may cause such effects in numans and/or that (2) captafol is very highly toxic to fish and may result in significant acute and chronic environmental adverse effects. Under 40 CFR 162.11(a)(4)(iii), the presumption initiating a Special Review for chronic oncogenic effects may be rebutted by proving "that the determination by the Agency that the pesticide meets or exceeds any of the criteria for risk was in error." Under 40 CFR 162.11(a)(4)(i), the presumption initiating a Special Review for acute wildlife effects may be rebutted by proving that "the formulation, packaging, method of use, and proposed restrictions on and directions for use and widespread and commonly recognized practices of use, the anticipated exposure to an applicator or user and to local, regional or national populations of nontarget organisms is not likely to

result in any significant acute adverse effects." Under 40 CFR 162.11(a)(4)(ii), the presumption initiating a Special Review for chronic wildlife effects may be rebutted by proving that "with proposed restrictions on use and widespread and commonly recognized practices of use, the pesticide will not concentrate, persist or accrue to levels in man or the environment likely to result in any significant chronic adverse effects."

E. BENEFITS INFORMATION

The Agency will perform a benefits analysis for captafol during Special Review. The following information briefly summarizes the most recent information on the benefits of captafol.

Chevron Chemical Company is the only producer of the technical product. Approximately 4.5 to 5 million pounds are used per year.

Captafol is a broad spectrum protectant fungicide used to control foliar diseases of certain fruits and vegetables. The major sites of use are apples, cherries, tomatoes, and citrus; more than half of the usage is for the first three crops. Minor use sites include the seed of corn, cotton, peanuts, rice, and sorghum; potato foliage; sweet corn; plums; watermelon; and cranberries; and use for wood preservation.

On apples captafol is used to control scab disease during the primary infection period, which lasts from the dormant period to the one-fourth green leaf stage of the apple tree's development. Captafol is used as a single application spray as an alternative to multiple applications of many of the registered alternative fungicides. The most

viable alternative fungicides include dichlone, captan, metiram, folpet, glyodin, thiram, maneb, triforine, mancozeb, zineb, diammonium EBDC, and a combination of thiophanate-methyl or benomyl with another fungicide to which resistance has not been demonstrated. Up to five applications of any one of the alternative fungicides may be required to prevent the primary stage infections which are often controlled with only one application of captafol.

Captafol is one of the most extensively used fungicides on sour cherries in the northcentral and eastern parts of the United States. It is used for control of leaf spot disease, brown rot blossom blight, and fruit brown rot. It is limited to use on cherries which are mechanically harvested because hand picking of cherries treated with captafol may result in allergic skin reactions. The most viable alternative fungicides for use on cherries are dichlone, dodine, and ziram, and benomyl used in combination with a fungicide against which fungal resistance has not been demonstrated. For brown rot blossom blight and fruit brown rot, additional alternative fungicides include captan, sulfur, and triforine. Glyodine, folpet, and zineb are available alternative fungicides for control of leaf spot on cherries.

Captafol is registered for control of anthracnose, early blight, late blight, gray leaf spot, nailhead spot, Septoria leaf spot, and fruit rot on tomtatoes. In California it is also registered for control of black mold. Because of the skin sensitization properties of captafol, it is also

limited to use on mechanically harvested tomatoes. These tomatoes are generally produced for processing rather than for the fresh market. Captafol is an extensively used fungicide on tomatoes. Twenty-six alternative fungicides are registered for control of one or more of the tomato diseases for which captafol is registered. The major ones include metiram, anilazine, captan, chlorthalonil, diammonium EBDC, folpet, maneb, nabam, metalaxyl combined with mancozeb, and zineb. For early blight, late blight, and anthracnose; metiram, anilazine, captan, chlorothalonil, diammonium EBDC, and maneb are the most viable.

In addition to submitting evidence to rebut the presumptions of risk in the Special Review, 40 CFR 162.11(a)(5)(iii) provides that a registrant or applicant "may submit evidence as to whether the economic, social and environmental benefits of the use of the pesticide subject to the presumption outweigh the risk of use." The benefits evidence submitted by registrants, applicants, and other interested persons will be considered by the Administrator when determining the appropriate regulatory action.

Registrants, applicants, or other interested persons who desire to submit benefits information should consider submitting information on the following subjects along with any other relevant information they desire to submit:

1. Biological and economic importance of captafol uses, including market studies and estimated quantities applied for those uses.

2. Alternative fungicides discussed in this document or any other which are available.

3. Nonchemical methods for all registered uses and application techniques, including any associated health effects and potential for water contamination.

4. The change in costs to captafol users for obtaining equivalent pest control with available substitute products or management techniques.

5. Assessment of the expected changes in level of disease control efficacy, crop yield, crop quality, crop injury, and environmental impacts associated with the use of alternative control measures.

6. Increased or reduced risks associated with the mixing, loading, applying, and disposing of alternative chemicals, and of other hazards associated with their potential increase in use if captafol is not available. Describe type of application equipment, protective clothing, and mixing/loading disposing procedures for the alternative chemicals.

7. Cultural practices and other factors that impact on farmworker exposure to captafol and any alternative cultural or Integrated Pest Management practices which might limit the use of captafol.

II. ADDITIONAL GROUNDS FOR REVIEW

In the Guidance Document EPA is requiring, pursuant to section 3(c)(2)(B) of FIFRA, that additional product chemistry, toxicology, ecological effects, residue chemistry, and

environmental fate studies of captafol be submitted. The Agency will review these studies to determine the extent to which other adverse effects may be associated with the use of this chemical.

III. HAZARDOUS WASTE DISPOSAL

The Agency is also investigating the wastes generated from manufacturing captafol and may regulate them as hazardous under the Resource Conservative and Recovery Act.

IV. REBUTTAL SUBMISSION PROCEDURES

All registrants and applicants for registration are being notified by certified mail of the initiation of the Special Review on their products containing captafol.

The registrants and applicants for registration will have 45 days after the date this notice is received or until (insert date 45 days after date of publication in the FEDERAL REGISTER) (whichever is later) to submit evidence in rebuttal to the Agency's presumption. Other interested parties may submit comments during the same period.

V. DUTY TO SUBMIT INFORMATION ON ADVERSE EFFECTS

Registrants are required by section 6(a)(2) of FIFRA to submit any additional information regarding unreasonable adverse effects on man or the environment which comes to their attention at any time. Registrants of captafol products must immediately submit any published or unpublished information, studies, reports, analyses, or reanalyses regarding any captafol effects

in animal species or humans, and claimed or verified accidents to humans, domestic animals, or wildlife which have not been previously submitted to EPA. These data should be submitted with a cover letter specifically identifying the information as being submitted under section 6(a)(2) of FIFRA. Registrants should notify EPA of any studies on captafol currently in progress, their purpose, the protocol, the approximate completion date, a summary of all results observed to date, the name and address of the laboratory performing the studies, and a statement as to whether these studies are being conducted in accordance with the Good Laboratory Practices published in the FEDERAL REGISTER of November 29, 1983 (48 FR 53946).

V. PUBLIC COMMENT OPPORTUNITY

During the time allowed for submission of rebuttal evidence, specific comments are solicited on the presumptions set forth in this Notice and in the Guidance Document. In particular, any documented episodes of adverse effects on humans or domestic animals should be submitted to the Agency. Any information as to any laboratory studies in progress or completed should be submitted to the Agency with a statement as to whether those studies are in compliance with the Good Laboratory Practices specified in 48 FR 53946. Specifically, information on any adverse toxicological effects of captafol, its impurities, metabolites, and degradation products is solicited. Similarly, submission of any studies or comments on the benefits from the use of captafol is requested. All

comments and information and analyses, which come to the attention of EPA, may serve as a basis for final determination of regulatory action following the Special Review.

All comments and information should be sent to the address given above, preferably in triplicate, to facilitate the work of EPA and others interested in inspecting them. The comments and information should bear the identifying notation [OPP-30000/43].

During the comment period, interested members of the public or registrants may request a meeting to discuss the risk issues and methods of reducing risks. Any records pertaining to such meetings, including minutes, agendas, and comments received will be filed under docket number OPP-30000/43.

Dated: 12/19/84

Director,
Office of Pesticide Programs.